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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,094	06/25/2003	Don J. Diamond	1954-410	7356

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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
05/15/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/603,094	DIAMOND, DON J.	
	Examiner	Art Unit	
	LOUISE HUMPHREY	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *3,4 and 12-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/13/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment and argument filed 13 April 2009. Claims 3, 4 and 12-14 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 1, 2 and 5-11 are pending and currently examined.

Information Disclosure Statement

The information disclosure statement (IDS) filed on 13 April 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner, as reflected by the attached dated and signed copy of 1449 form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. §112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1, 2 and 5-11 under 35 U.S.C. §112, second paragraph, as being indefinite is **withdrawn** in response to the Applicants' amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1, 2, 5, 6 and 9-11 under 35 U.S.C. §103(a) as being obvious over Prieur *et al*. (WO 98/26074) in view of Livingston *et al*. (1999) is **withdrawn** in consideration of Applicants' argument.

The rejection of claims 1, 2 and 5-11 under 35 U.S.C. §103(a) as being obvious over Prieur *et al*. (WO 98/26074) in view of Livingston *et al*. (1999) and Krieg *et al*. (WO 01/22972) is **withdrawn** in consideration of Applicants' argument.

Response to Arguments

Applicant's arguments with respect to claims 1, 2 and 5-11 have been considered but are moot in view of the **new grounds of rejection**.

NEW REJECTIONS

Claims 1, 2, 5, 6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prieur *et al*. (WO 98/26074, No. F in IDS filed 08 March 2004, hereinafter "Prieur") in view of Alexander *et al*. (1994, No. H in IDS filed 08 March 2004, hereinafter "Alexander") and Fikes *et al*. (WO 99/58658, hereinafter "Fikes").

Prieur discloses a vaccine or a pharmaceutical composition comprising a fusion protein comprising cytomegalovirus (CMV) CTL epitope, a HLA-DR restricted peptide (Abstract and Claims), NLVPMVATV (Figure 4), which matches the claimed CMV CTL epitope pp65 (residues 495-503) identified by SEQ ID NO:1.

Prieur does not disclose the fusion partner of a T helper epitope.

Alexander discloses Pan DR epitope peptides (PADRE), which elicit optimal T helper responses as well as facilitate the generation of cytotoxic T lymphocyte (CTL) responses and are approximately 1000 times more powerful than natural T cell epitopes (see Abstract and pages 755-758). Alexander further suggests using PADRE peptides in the development of subunit vaccines (Abstract).

Alexander does not explicitly disclose fusing PADRE to CTL epitope in a vaccine.

Fikes discloses nucleic acid vaccines expressing a fusion peptide (page 6, lines 24-33) comprising a T helper epitope, with the specific embodiment of PADRE (page 7, lines 24-33; and page 17, lines 12-13), and a CTL epitope, with a specific embodiment of CMV (page 16, line 24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Prieur's CMV fusion peptide vaccine by fusing the HCMV pp65 CTL epitope to a PADRE as suggested by Alexander and Fikes. The skilled artisan would have been motivated to do so to enhance the amount of T helper and CTL immune response elicited by the HCMV pp65 CTL epitope. There would have been a reasonable expectation of success, given the disclosure that PADRE peptides elicit optimal T helper responses as well as facilitate the generation of cytotoxic T lymphocyte (CTL) responses and are approximately 1000 times more powerful than natural T cell epitopes, as taught by Alexander, and further based on the disclosure that it is known in the art to fuse a CTL epitope with a T helper epitope to make a peptide vaccine or to be expressed by vectors, as taught by Fikes. Thus, the invention as a

whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prieur *et al*. (1998, WO 98/26074, hereinafter "Prieur") in view of Fikes *et al*. (WO 99/58658, hereinafter “Fikes”) and Krieg *et al*. (WO 1212972, 30 April 2001, hereinafter "Krieg").

The instant claims are directed to an unlipidated cytomegalovirus (CMV) vaccine comprising a fusion protein comprising a T helper epitope (T_H) fused to a CMV CTL epitope pp65 (residues 495-503) identified by SEQ ID NO:1, which is a nonameric peptide of the sequence NLVPMVATV, and further comprising a DNA adjuvant.

The disclosure of Prieur and Fikes is set forth above. Neither Prieur nor Fikes discloses a DNA adjuvant.

Krieg describes immunostimulatory nucleic acids. Specifically, Krieg discloses the instantly claimed DNA adjuvant of SEQ ID NO:10. See page 57, SEQID NO:959, in Table A.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the unlipidated CMV $pp65_{495\text{-}503}$-T_H fusion peptide vaccine by adding a DNA adjuvant as taught by Krieg as routine optimization of a vaccine. The skilled artisan would have been motivated to do so to enhance the amount of immune response elicited by the nonameric CMV pp65 CTL epitope. There would have been a reasonable expectation of success, given that these DNA adjuvants

preferentially activate non-rodent immune cells such as B cells, natural killer cells and monocytes, as taught by Krieg. Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. H./
Examiner, Art Unit 1648

/Jeffrey S. Parkin/
Primary Examiner, Art Unit 1648

29 April 2009